REMARKS

The examiner is thanked for the entry of amendments and consideration of remarks.

Claim disposition

Claims 16 and 17 are cancelled, and claims 1 and 19 are amended. Applicants hereby reserve the right to file continuation applications or take any other such appropriate measure to prosecute the amended or cancelled subject matter.

New claims 20-23 are added.

Claims 1-3, 5, 6, 10, 16, and 19-23 will be pending in the application upon entry of this amendment.

Withdrawal of the rejections under 35 U.S.C. § 112, first paragraph, is respectfully requested

Claims 1-3, 5, 6 and 10, 16, 17, and 19 were rejected under 35 U.S.C. § 112, first paragraph for non-enablement; the Office Action indicating that it is a concern of the examiner as to how it can be concluded that the effect of a test compound on Erk-2 expression is indicative of a compound having gabapentinoid activity. The Office Action further indicates that due to lack of guidance and working examples of compound having gabapentin activity which act via Erk-2activation as well as the inability to predict that the compounds, other than gabapentin, which act via Erk-2 would, in fact, have gabapentin activity leads the Examiner to beconclude that undue experimentation would be required to practice the invention as claimed. The Office Action requests clarification of this issue.

While it is noted that enablement does not require a teaching of how the invention works, and that it does not require working examples of every permutation of the invention, to facilitate prosecution and the allowance of the claims under consideration, independent claims 1 and 19 are amended to include a limitation drawn to "...a test compound that binds to the $\alpha_2\delta$ subunit of a calcium channel ...". See amendment to step c), claims 1 and 19. Support for this amendment of claim 1 includes the recitation on page 2, lines 16-20 of the specification,

stating "test substances" and "test compound" in the context of screening for gabapentinoid activity; and on page 11, lines 1-3 of the specification which incorporates the publication WO 99/21824 (refrred to as WO '824 hereinafter) by reference, in the context of target compounds to be screened in the assays of the present invention. More particularly, WO '824 provides the statements that "...Gabapentin, binds to the $\alpha_2\delta$ subunit of a calcium channel...", and that "...the compounds of the instant invention also bind to the subunit...".
of see page 9, final paragraph of the specification.

It is also noted that at the time of filing this application, methods of determining the $\alpha_2\delta$ subunit binding was well known in the art; including, for example, those described in Gee et al. (1996), Journal of Biological Chemistry, 271(10): 5768-5776, copy attached herewith.

Thus, to facilitate prosecution independent claims 1and 19 now reciting "...a test compound that binds to the $\alpha_2\delta$ subunit of a calcium channel..." is so limited in scope to utilizing compounds that, like gabapentin and other compounds such as those represented in WO '824, also possess this binding capability. Accordingly, not every compound that inhibitsErk-2 activation is identified as a gabapentinoid. As such, applicants respectfully submit that there would be no undue experimentation required in carrying out the invention of the claims under consideration, that the specification fully teaches how to make and use the claimed invention, and that the claims are commensurate in scope with the teachings of the specification.

Furthermore, new claims 20-23 are submitted herewith. Support for new independent claim 20 is provideded of page 11, lines 1-3 of the specification which incorporates the WO '824 publication by reference; and by, for example, page 2, lines 10-20 of page 2 of the WO '824 publication. New independent claim 20 restricts "target compounds" to be utilized in the claimed method to the specific structures defined in the claim. New claims 21-23 are dependent on claim 1and further recite limitations directed to level of inhibition of the Erk-2 activation in a compound identified as a gabapentinoid in comparison to controm levels as claimed. Support for new claims 20-23 is found, for example, on page 11, lines 25-29.

Accordingly, in light of all of the above, Applicants submit that this rejection of the claims under consideration is obviated and should not be extended to the new claims.

Claims 1-3, 5, 6 and 10, 16, 17, and 19 were rejected under 35 U.S.C. § 112, first paragraph, the Office Action alleging that there is a conflict between claims 1 and 16 as claim 1 does not require overexpression of NK-1, where claim 16 does. Based on this rationale, the Office Action states that it appears that only methods in which the cells over-express NK-1, or possibly NK receptors in general are enabled. The Office Action requests clarification in this regard.

This rejection is respectfully traversed. Applicant submits that the above-stated overexpression in claim 16 is an alternative embodiment and does not present conflict between the two claims. See for example, lines 16-20 of page 15 of the specification clearly stating: "In another embodiment of the method, NK or mGluR expressing cells and treated with compounds and agonist as above, cells are then harvested and Erk-2 phosphorylation determined..." (emphasis added). In contrast, lines 14-18 on page 14 of the specification states: "Alternatively, Erk-2 phosphorylation may be followed in cells that have intact MAPK signaling pathways where either NK or mGluR receptors are overexpressed.... (emphasis added)". Accordingly, applicant submits that present claim 1 is fully enabled.

In light of all of the above, Applicants respectfully request that this rejection under 35 U.S.C. § 112, first paragraph, be withdrawn and not extended to the new claims.

Withdrawal of the rejections under 35 U.S.C. § 112, second paragraph, is respectfully requested

Claims 1-3, 5, 6, 10 and 19 were rejected under 35 U.S.C. § 112, second paragraph, for lack of a conclusion step. To facilitate prosecution, such a conclusion step is added to independent claims 1 and 19, and included in new claim 20. Please see step g) of said claims reciting: "...identifying as a gabapentinoid, a test compound that shows greater inhibition of said reporter polypeptide activity in said first group of step f) than said reporter polypeptide activity of said second group in step f)...". Support for this amendment can be found throughout the specification as originally filed. For example, see specification page 11, lines 23-29.

Accordingly, Applicants respectfully request that this rejection of the claims under consideration under 35 U.S.C. § 112, second paragraph, is obviated.

Claims 1-3, 5, 6, 10, 16, 17, and 19 were rejected under 35 U.S.C. § 112, second paragraph, for recitation of "target compound", the Office Action alledging that it is not clear what is being targeted. As suggested by the Examiner, and as explained above, claims 1 and 19 are amended to recite "test compound". Also as explained above, new claim 20 recites "target compounds"; however, the claim also restricts "target compounds" to be utilized in the claimed method to the specific structures defined in the claim. Accordingly, this rejection of the claims under consideration under 35 U.S.C. § 112, second paragraph, is obviated and should not be extended to the new claims.

Claims 1-3, 5, 10, and 19 were rejected under 35 U.S.C. § 112, second paragraph, for The use of "at least two groups" or a "plurality" of groups; the office Action indicating that no steps have been recited in order to clearly explain how to use more than two groups. This rejection is respectfully traversed. Applicants submit that the use of the open-ended claim language is completely clear as understood by one of ordinary skill in the art. The claims encompass a method in which only the two groups are utilized according to the claimed method; as well as a method in which more than the two groups are utilized, so long as the two groups are included in the method. Clearly, such interpretation is consistent with any variation that one of ordinary skill in the art can select to include in practicing the claimed invention, in light of the teachings of the present specification and claims. Such variation may be routine; for example, the artisan selecting to include several concentration of a test compound. However, even if the variation is not routine, Applicant submits that further variation of the claimed method by including more than the two groups, for any reason, should be considered within the claimed invention; so long as each element of the claim is satisfied. Accordingly, Applicants respectfully request that this rejection of the claims under consideration under 35 U.S.C. § 112, second paragraph, be withdrawn and not extended to the new claims.

Claims 16, and 17 were rejected under 35 U.S.C. § 112, second paragraph, the Office Action indicating that the kit claims under consideration omits an essential element. While Applicants submit that a kit claim comprising only one element drawn to a particular cell line, is not necessarily incomplete for omitting essential elements, these claims are cancelled to facilitate prosecution and allowance of the remaining claims under consideration.

In light of all of the above, Applicants respectfully request that this rejection under 35 U.S.C. § 112, second paragraph, be withdrawn and not extended to the new claims.

In view of the foregoing, further and favorable action in the form of a Notice of Allowance is believed to be next in order, and such action is respectfully solicited.

The Commissioner is hereby authorized to charge any fees under 37 C.F.R. §§ 1.16 and 1.17 that may be required by this paper to Deposit Account No: 23-0455.

In the event the Examiner wishes to discuss any matter concerning this application, he is welcomed to communicate with the undersigned by telephone.

Respectfully submitted,

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